

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 28, 2020

Rebecca Mannion Agent Ameriplus Inc. 535 S. Hercules Avenue, Suite 201 Clearwater, FL 33764

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: 2.2% Sodium Hypochlorite Solution

EPA Registration Number: 88049-2 Application Date: February 13, 2020

Decision Number: 561189

Dear Ms. Mannion:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
      - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped, enveloped.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus Type 37 (ATCC VR-1147) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at <a href="mailto:disinfectantslist@epa.gov">disinfectantslist@epa.gov</a>.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Inyderman

Enclosure: stamped label

# 2.2% Sodium Hypochlorite Solution

**ACTIVE INGREDIENT:** Sodium Hypochlorite......2.2% OTHER INGREDIENTS: 97.8% TOTAL: ...... 100.0%

Available Chlorine 2.13%

# **KEEP OUT OF REACH OF CHILDREN CAUTION**

See back panel for other precautionary statements

FIRST AID		
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.		
If on Skin or Clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a Poison Control Center or doctor for further treatment advice.</li> </ul>	
If in Eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after 5 minutes and then continue rinsing eye.</li> <li>Call a Poison Control Center or doctor for further treatment advice.</li> </ul>	
For omorgones	vinformation, call the National Pesticides Information Center at 1-800-858-7378, from	

For emergency information, call the National Pesticides Information Center at 1-800-858-7378, from 6:30 a.m. to 4:30 p.m. Pacific Time (PT), seven days a week. During other times, call the Poison Control Center at 1-800-222 1222.

EPA Reg. No. 88049-2

EPA Est. No.

[manufactured] [distributed] [by:] [for:] Ameriplus, Inc. 535 S. Hercules Ave., Suite 201 Clearwater, FL 33764

ACCEPTED 04/28/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

88049-2

#### **Net Contents:**

# PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals

CAUTION. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Causes moderate eye irritation.

#### **Environmental Hazards**

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **Physical and Chemical Hazards**

This product contains bleach. Mixing this product with any other cleaning products such as ammonia, toilet bowl cleaners, or other chemicals may release hazardous gases irritating to eyes, lungs and mucous membranes.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal, or cleaning of equipment.

**Pesticide Storage:** Store this product in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

**Pesticide Disposal:** Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Then, offer for recycling, if available, or place in trash collection.

### [List of approved organsims]

[ATCC numbers are required on the master label, but are not required to be listed on the production label.]

#### **Bactericidal**

Salmonella enterica [ATCC 10708] Staphylococcus aureus [ATCC 6538]

#### Virucidal

Influenza A virus [ATCC VR-1469] Rhinovirus type 37 [ATCC VR-1147]

# **Fungicidal**

Aspergillus brasiliensis [(mildew)] [ATCC 16404] Trichophyton interdigitale [(Athlete's foot fungus)] [ATCC 9533]

#### Nonfood contact sanitizer

Staphylococcus aureus [ATCC 6538] Enterobacter aerogenes [ATCC 13048]

[Optional Claims: Choose from the following claims as appropriate, location optional:]

- 100% satisfaction or your money back guaranteed
- All Purpose Cleaner with Bleach
- Bleaching action makes tough stains & grease disappear
- Cleans & [and] deodorizes surfaces
- Cleans & [and] disinfects
- Contains Chlorine Bleach
- Cuts through grease and grime
- Degreaser
- Deodorizes
- Deodorizes and has a fresh scent
- Disinfectant
- Disinfects [&] and Deodorizes
- Disinfects [with bleach]
- Dissolves Tough Soap Scum
- Effective against *Aspergillus brasiliensis* (mildew) and *Trichophyton interdigitale* (athlete's foot fungus) on hard non-porous surfaces in 10 minutes.
- Effective against Influenza A Virus [ATCC VR-1469] and Rhinovirus type 37 [ATCC VR-1147] in 30 seconds.
- Effective against Salmonella enterica [ATCC 10708] and Staphylococcus aureus [ATCC 6538]
- Effective against Salmonella enterica [ATCC 10708], Staphylococcus aureus [ATCC 6538], and Enterobacter aerogenes [ATCC 13048] in 30 seconds.
- Effective against Salmonella enterica [ATCC 10708], Staphylococcus aureus [ATCC 6538], Enterobacter aerogenes [ATCC 13048], Influenza A Virus [ATCC VR-1469], [and] Rhinovirus type 37 [ATCC VR-1147] in 30 seconds.
- For use in [the] home[s] [and] [schools] [and] [offices] [and] [institutions]
- Great for cleaning glazed porcelain, glazed ceramic and plastic laminates
- Kills [elimates] [Flu virus] [or] [Influenza A virus] [and / or] [Rhinovirus type 37]
- Kills [eliminates] [common] [household] germs [including:] [insert organisms from above]

{The following claims may list the organisms next to the claim or list with a linking symbol on any panel}

- Kills [eliminates] [removes] 99.9% of [common] [household] [germs] [:] Salmonella enterica, Staphycloccous aureus, Enterobacter aerogenes, Influenza A virus, Rhinovirus type 37
- Kills [eliminates] [removes] 99.9% of bacteria [:] Salmonella enterica, Staphycloccous aureus, Enterobacter aerogenes
- Kills [eliminates] [removes] 99.9% of bacteria and viruses [:] Salmonella enterica, Staphycloccous aureus, Enterobacter aerogenes, Influenza A virus, Rhinovirus type 37
- Kills [eliminates] mold [&] and mildew
- Kills [eliminates] viruses
- Kills [insert organisms from above]
- Kills [Salmonella enterica] [and / or] [Staphylococcus aureus]
- Kills athlete's foot fungus on hard non-porous surfaces
- Kills mildew [&] and cleans soap scum
- Mildew & Soap Scum Remover
- Mold & Mildew Remover
- Removes bathroom stains
- Removes stains & disinfects
- · Removes stains and cleans surfaces
- Removes stains and soap scum from sealed grout, glazed ceramic tile and plastic without scrubbing.
- Removes tough stains & disinfects
- Removes tough stains, grease and deodorizes with a fresh scent
- Rinse or wipe clean
- Sanitizer [sanitizes] [sanitizing]
- Soap Scum Remover
- Soap Scum Remover is specifically formulated for use on: washable bathroom & kitchen surfaces
  and fixtures that would not be damaged by bleach including tile, sealed grout, tub, sinks, toilet
  bowls, shower walls & doors, vinyl shower curtains, vinyl bath mats, fiberglass, plastic & vinyl
  outdoor and patio furniture, pool & spa tile.
- Stain & Grease Remover
- Store and transport in an upright position.
- Tough on Mildew Stains
- With bleach

## **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

- 1. Read entire label before use.
- 2. Turn nozzle to on position.
- 3. [Use only in well ventilated areas.] *or* [Use in well ventilated areas. Avoid prolonged breathing of vapor.]
- 4. Reclose sprayer for storage.
- 5. Wash hands after use.

**Use to Clean** and deodorize bathroom tile, grout, fiberglass showers, vinyl bath mats and shower curtains, garbage cans, diaper pails, and to prepare surfaces for painting. Spray directly on area to clean and wait a few minutes for stains to disappear. For soap scum, allow to penetrate (but not dry) and wipe clean. Rinse and repeat if necessary.

[To remove mildew stains: spray product onto stains and wait until stains disappear, then rinse well. To remove tough stains and soap scum: spray product onto stains and soap scum. Let stand for several minutes. Wipe with sponge and rinse well.]

**Use to Disinfect** and deodorize hard non porous surfaces made of plastic, vinyl, Formica, glass, and glazed ceramic, glazed porcelain, baked enamel, and sealed stone including bathroom floors, glazed tile[s], outside surfaces of toilet, sinks, diaper pails, garbage cans, kitchen counters and floors. Remove gross filth or heavy soil prior to disinfecting. Spray surface until thoroughly wet, allow to stand for 30 seconds. Rinse and air dry.

To kill mildew and athlete's foot fungus on hard non-porous surfaces, allow product to stand for 10 minutes before rinsing.

**Use to [Clean] [and] Sanitize** hard[,] nonporous nonfood surfaces

Spray surface until thoroughly wet, allow to stand for 30 seconds. Rinse and air dry.

Avoid contact with wood or painted surfaces you do not intend to repaint. **Avoid contact with metal or unglazed porcelain.** Do not allow this product to come in contact with clothing, carpeting, or other fabrics which may become discolored or damaged.

[optional graphics]



### **Emerging Viral Pathogens Claims**

{This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Non-enveloped viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus type 37 [ATCC VR-1147]
Large non-enveloped virus	Rhinovirus type 37 [ATCC VR-1147]

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Rhinovirus type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

{OR}

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Rhinovirus type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.